Special 510(k) Summary

APR – 7 2009

Submitter's Name/Address
Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Contact Person
Linda Morris
Senior Regulatory Specialist, MS 2-11
Regulatory Affairs
(972) 518-6711
Fax (972) 518-7479

Date of Preparation of this Summary:	December 15, 2008
Device Trade or Proprietary Name:	Creatinine
Device Common/Usual Name or Classification Name:	Creatinine Reagent
Classification Number/Class:	Class II 862.1225
Product Code:	CGX

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990, 21 CFR 807.92, and the guidance document, "The New 510(k) Paradigm, Alternate Approaches to Demonstrating Substantial Equivalence in Pre-market Notification" dated March 20,1998.

The assigned 510(k) number is: K083809.

Test Description:

Creatinine is an in vitro diagnostic assay for the quantitative analysis of creatinine in human serum, plasma, or urine. At an alkaline pH, creatinine in the sample reacts with picrate in the reagent to form a creatinine-picrate complex. The rate of increase in absorbance at 500 nm due to the formation of this complex is directly proportional to the concentration of creatinine in the sample.

Substantial Equivalence:

The modified Creatinine assay is substantially equivalent to the cleared Creatinine assay (K061193) on the Abbott AEROSET® System and ARCHITECT® *c*Systems. The modifications to the urine application include changes to the calibration and assay parameters. The Use-factor calibration has been changed to a Linear calibration that allows for a separate urine calibration curve. In addition, the modified Creatinine assay urine application uses NIST SRM 914 as the reference standard rather than the serum standard, NIST SRM 967, both of which are IDMS traceable standards. These modifications did not significantly change the safety and effectiveness profile of the device as demonstrated in the Performance Characteristics Summary.

The modified Creatinine assay urine application is substantially equivalent to the Roche Creatinine assay urine application (K941837) on the Hitachi 917 Analyzer. Both assays yield similar Performance Characteristics.

Similarities:

- Both assays can be used for the quantitation of creatinine.
- Both assays yield similar results.
- Both assays are based on the modified Jaffe (creatinine alkaline picrate) methodology.
- Both assays use serum, plasma, and urine

Differences:

None

Intended Use:

The Creatinine assay is used for the quantitation of creatinine in human serum, plasma, or urine.

Performance Characteristics:

Comparative performance studies were conducted using the AEROSET System and the ARCHITECT *c*8000 System. The Creatinine assay urine application method comparison yielded acceptable correlation with the Roche Creatinine assay urine application on the Hitachi 917 Analyzer. The urine application on the AEROSET System showed a correlation coefficient of 0.9992, slope of 1.01, and Y-intercept of –0.43 mg/dL when compared to the Roche Creatinine assay urine application on the Hitachi 917 Analyzer. The urine application on the ARCHITECT *c*8000 System showed a correlation coefficient of 0.9990, slope of 0.97, and Y-intercept of 0.36 mg/dL when compared to the Roche Creatinine assay urine application on the Hitachi 917 Analyzer. The urine application on the ARCHITECT *c*8000 System showed a correlation coefficient of 0.9992, slope of 0.96, and Y-intercept of 1.23 mg/dL when compared to the AEROSET System. The Creatinine assay method comparison yielded acceptable correlation between the AEROSET System and the ARCHITECT *c*8000 System for the urine application.

The Creatinine assay is linear from 5.00 to 740.00 mg/dL for the urine application. The limit of quantitation (sensitivity) of the Creatinine assay is 5.00 mg/dL for the urine application.

Precision studies conducted using the Creatinine assay urine application on the ARCHITECT *c*8000 System showed the total %CV for Level 1 to be 1.34%, and for Level 2 to be 1.27% for the urine application.

These data demonstrate that the performance of the Creatinine assay urine application is substantially equivalent to the performance of the Roche Creatinine assay urine application on the Hitachi 917 Analyzer.

Conclusion:

The Creatinine assay urine application on the AEROSET System and the ARCHITECT *c*8000 System is substantially equivalent to the Roche Creatinine assay urine application on the Hitachi 917 Analyzer as demonstrated by results obtained in these studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Abbott Laboratories
c/o Linda Morris
Senior Regulatory Specialist,
1921 Hurd Drive
Irving, TX 75038

APR - 7 2009

Re: k083809
Trade/Device Name: Creatinine
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine test system
Regulatory Class: Class II
Product Code: CGX
Dated: March 7, 2009
Received: March 10, 2009

Dear Linda Morris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indication for Use

510(k) Number (if known): K083809

Device Name: Creatinine

Indication For Use:

A creatinine test system is a device intended to measure creatinine levels in serum, plasma and urine. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

Prescription Use X And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K083809